REMARKS

Reconsideration of the rejections set forth in the Office Action dated July 19, 2006, is respectfully requested. Claims 85, 86, 99, 100, 114, 116, 133, and 135 have been amended to correct a typographical error. Therefore, no new matter has been added with these amendments. Claims 85-152 remain pending.

Specification

Applicant has amended the relate-back statement to claim priority as follows: This application is a continuation of U.S. Application Serial No. 09/638,241, filed August 14, 2000, which claims priority from U.S. Provisional Patent Application Serial No. 60/148,913, filed August 13, 1999. U.S. Application Serial No. 09/638,241 is also a continuation-in-part of International Patent Application No. PCT/US00/14708, filed May 30, 2000, which is a continuation-in-part of and claims the benefit under 35 USC §119 of U.S. Application Serial No. 09/322,516, filed May 28, 1999, now U.S. Patent No. 6,245,107. A request for corrected filing receipt is filed herewith.

Art Rejections

Claims 85-152 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bao et al. (USP 6,224,630). The Examiner has taken the position that Bao describes a method for treating an anulus fibrosus (also referred to as "annulus fibrosis") comprising all the steps as claimed except for the step of using a porous mesh having the configuration as claimed. Furthermore, the Examiner has taken the position that having the configuration as claimed is well known in the art of patching and closing wounds. In support of this "well-known statement," the Examiner cited five references: Ruiz (USP 5,976,174), Diaz (USP 5,690,674), Bao et al. (USP 5,192,326), Eberbach (USP 5,116,357), and Flament et al. (USP 6,180,848).

Each of claims 85-113 is limited to an implant or porous mesh that "*expands radially by*

reducing the length between the distal and proximal ends." In order to explain the significance of this distinction and why one skilled in the art would rule out as inapplicable the references cited by the Examiner, Applicant submits herewith the Declaration of Bret Ferree, M.D., a Board Certified orthopedic surgeon who specializes in spinal surgery. He has performed over 1,500 surgeries to repair disc herniations and is therefore familiar with the types of devices that can and cannot be used to repair defects in the anulus fibrosus. Ferree Decl., ¶ 4.

Applicant respectfully submits that none of the cited references teach or suggest all of the limitations of claims 85-113. As acknowledged by the Examiner, Bao (USP 6,224,630) does not teach or suggest an implant or porous mesh that "*expands radially by reducing the length between the distal and proximal ends.*"

The Examiner has taken the position that Ruiz (USP 5,976,174) describes a porous mesh used to plug or patch the defect hole in tissue with the claimed characteristics. See Office Action, Page 2. The device described in Ruiz is a "flexible tube that is inserted through the hole and then radially expanded on either side of the hole. Expansion of the ends of the tube causes a mid-region of the tube to contact and conform to the dimensions of the hole, and to exert a radial force along the edge of the hole, thereby sealing it." (emphasis added) Col. 2, lines 47-52. Dr. Ferree, however, explains that a surgeon would not use such a device to repair a disc herniation because of the hourglass shape of the implant. In a majority of patients, the enlarged portion of the device would extend from the posterior side of the anulus fibrosus and would compress or otherwise injure the nerves that overly the posterior surface of the disc. Ferree Decl., ¶ 8. Furthermore, Dr. Ferree explains that the Ruiz device could not withstand the high pressures found in the intradiscal space, which are generally above 750 mmHg and can be as high as 17,251 mmHg. Ferree Decl., ¶ 9. The Ruiz device is designed to treat cardiac septal defects and is delivered percutaneously. Intravascular pressure is on average 120 mmHg (systolic)/80 mmHg (diastolic). Ferree Decl., ¶ 9. Although blood pressure can, in extreme cases, be as high as 300 mmHg (systolic)/160 mmHg (diastolic), these pressures are still far lower than the 750 - 17,251 mmHg pressure found in the intradiscal space. See Ferree Decl., ¶ 9. Because the Ruiz device must be thin and flexible to enable it to be delivered through tortuous vascular anatomy before reaching the heart, it must be thin and flexible.

Ferree Decl., ¶ 9. These characteristics prevent the Ruiz device from functioning correctly in an intervertebral disc because it could not withstand the high pressures. Ferree Decl., ¶ 9. Therefore, a skilled surgeon would reject the proposed combination of Ruiz and Bao.

The Examiner has taken the position that Diaz (USP 5,690,674) "teaches the wound closure plug" with the claimed characteristics. Office Action, Pages 2-3. The Diaz device is a biodegradable plug with a proximal retainer and a distal retainer coupled by a waist that may be positioned to straddle a wound in a blood vessel wall. See Abstract. In his Declaration, Dr. Ferree explains that, similar to Ruiz, the Diaz device has an enlarged portion that would, if the device were used to repair a ruptured disc, remain on the posterior side of the anulus fibrosus and curve and extend outwardly in a posterior direction. Ferree Decl., ¶ 10. Therefore, in a majority of patients, the Diaz device would press against and injure the delicate nerves that overly the posterior surface of the disc. Ferree Decl., ¶ 10. Furthermore, because this device is designed to plug a wound in a blood vessel wall, the Diaz device is only intended to withstand intravascular pressures, which are on average 120 mmHg (systolic)/80 mmHg (diastolic). Ferree Decl., ¶ 11. Although blood pressure can, in extreme cases, be as high as 300 mmHg (systolic)/160 mmHg (diastolic), these pressures are still far lower than 17,251 mmHg pressure found in the intradiscal space. Ferree Decl., ¶ 11. Therefore, a skilled surgeon would not use the Diaz device to repair defects in the anulus fibrosus.

The Examiner has taken the position that Bao et al. (USP 5,192,326) "teaches a porous membrane that's expanded to seal a hole" with the claimed characteristics. Office Action, Page 3. Bao describes a "prosthetic nucleus for implantation in the disc space after removal of a damaged or degenerated nucleus." Abstract. Bao teaches to partially or totally replace the herniated nucleus with the prosthetic hydrogel nucleus. See Col. 13, lines 56-60. In his Declaration, Dr. Ferree explains that, to the extent that any portion of the nucleus remains, the Bao device would not retain the nucleus pulposus. Ferree Decl., ¶ 13. It is well known that, when implanted clinically, hydrogel devices have been found to not contain the nucleus pulposus within the disc. Ferree Decl., ¶ 13. In fact, not only do hydrogel devices fail to contain the nucleus pulposus within the disc, the hydrogel device itself may actually extrude from the disc. Ferree Decl., ¶ 13. Therefore, a skilled orthopedic surgeon, who is seeking to repair a disc herniation, would avoid devices as described in Bao.

Furthermore, the Bao device is a hydrogel device that expands in all directions. Ferree Decl., ¶ 14. Therefore, it does not meet the claim limitation of "*[expanding] radially by reducing the length between the distal and proximal ends.*"

The Examiner has taken the position that Eberbach (USP 5,116,357) describes "hernia plug/patch having configuration as claimed." Office Action, Page 3. Eberbach describes a device for repair of hernias including a plug positionable in an opening in the abdominal wall and a patch positionable over a weakened portion of the abdomen adjacent the opening. See Abstract. Dr. Ferree explains that the approach described in Eberbach of using a bulky patch and plug positioned on the outside of the defect would be rejected by a skilled surgeon. Ferree Decl., ¶ 15. In a majority of patients, implantation of such a device would cause the same problems of compressing and injuring delicate nerves that overly the posterior surface of the disc. Ferree Decl., ¶ 15. Furthermore, Eberbach lists polypropylene and nylon as examples of materials that can be used to make the patches. See Col. 5, lines 34-43 and Ferree Decl., ¶ 16. In his Declaration, Dr. Ferree explains that a skilled orthopedic surgeon would have rejected a device made of polypropylene because this material is known to promote formation of adhesions. Ferree Decl., ¶ 16. Adhesions that form on the outside of the anulus would fuse with the nerve and thus tether the nerves to the disc. This joining of the nerve to the disc would result in injury to the nerves that overly the posterior surface of the disc during normal spinal movement. Ferree Decl., ¶ 16. Additionally, Dr. Ferree states that the Eberbach device would be rejected because it could not withstand the high pressures found in the intradiscal space. Ferree Decl., ¶ 15.

The Examiner has taken the position that Flament et al. (USP 6,180,848) describes "a mesh having configuration as claimed for patching/covering a hernial canal." Office Action, Page 3. Flament describes a device for obturating a hernial canal, the device having a first part extending through the hernial canal and a second part for covering the internal orifice of the hernial canal. See Abstract. None of the devices described in Flament are positioned "*distally beyond the outer later of the annulus fibrosis,*" as required by the claims. In his Declaration, Dr. Ferree explains the importance of placing the implant beyond the outermost layer of the anulus fibrosus. Ferree Decl., ¶ 18. Such placement "allows the outer layer of the anulus fibrosus to act as a stabilizer and cushion

between the edges of the implanted device and the nerves. Cushioning and stabilizing are particularly important in light of the large compressive forces applied to the device in the intradisc space. Spinal devices are exposed to large extrusion forces from the nucleus pulposus and large axial compression forces from the vertebra above and below the device. It is imperative to keep the device from migrating even one millimeter towards the nerves." Ferree Decl., ¶ 18. Compression on the sides of the Flament device will tend to force a portion of the device out of the aperture and into what would be the nerves if the Flament device was used to treat a herniated disc, as suggested by the Examiner. See Ferree Decl., ¶ 18. The asserted combination would therefore have been rejected by those skilled in the art.

With respect to claims 114-152, each of these claims requires the steps of "*providing a first elongate fastening member having a first end region, a second end region, and an anchor on the first or second end regions, the anchor being substantially transverse when deployed*" and "*securing the first end region of the first elongate fastening member to the [porous mesh or implant] and securing the second end region of the first elongate fastening member to the annulus fibrosis.*" Applicant respectfully submits that none of the cited references teach or suggest methods for treating a defect in an anulus fibrosus having all of the limitations of claims 114-152.

Bao et al., U.S. Patent No. 6,224,630, states that anchoring devices may be used to affix the implant to the annulus to prevent migration. See Col. 14, lines 17-19. Examples of anchoring devices include tines for impregnation, surgical fixation techniques such as biodegradable sutures, staples, fibrin sealants, and surgical glues. See Col. 14, lines 19-29. There is no teaching or suggestion, however, to use elongate fixation devices with an anchor that is substantially transverse when deployed, a required by claims 114-152.

Several of the other cited references also mention that the device may be anchored using sutures. Eberbach, U.S. Patent No. 5,116,357, notes that the contents of the abdominal cavity may be sufficient to apply adequate pressure to hold the patches in proper position, but also states that the patch may be secured with sutures or staples. Additionally, Flament, U.S. Patent No. 6,180,848, notes that the implant may be sutured in place. See, e.g., Col. 3, lines 17-28 and lines 24-61. There is no teaching or suggestion, however, to use elongate fixation devices with an anchor that is

substantially transverse when deployed, as required by claims 114-152.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,

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